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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,727	07/15/2003	Wouter E. Roorda	50623.211	7043
<div>7590 Cameron Kerrigan Squire, Sanders &amp; Dempsey L.L.P. Suite 300 One Maritime Plaza San Francisco, CA 94111</div>			<div>EXAMINER AZPURU, CARLOS A</div>	
			<div>ART UNIT 1615</div>	<div>PAPER NUMBER</div>
			<div>MAIL DATE 06/07/2007</div>	<div>DELIVERY MODE PAPER</div>

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/619,727	<b>Applicant(s)</b> ROORDA ET AL.	
	<b>Examiner</b> Carlos A. Azpuru	<b>Art Unit</b> 1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 March 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 5,7,13,14 and 17-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4,6, 8-12, 15 and 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Receipt is acknowledged of the amendment filed 03/19/2007.

The following rejection is maintained in this action:

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 6, 8-12, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 970 711 A2 (Ethicon Inc).

Ethicon Inc disclose polymer coated stents (see Abstract). Non-acrylic polymers such as vinyl halides, polystyrenes and polyoxymethylenes are disclosed for their use in these polymer coatings at [0023]. Multiple coatings are suggested at [0028], with a topcoat suggested at [0029] in order to delay release of the pharmaceutical agent. Anti-inflammatories are set out at [0030]. While Ethicon Inc differs in its lack of specific disclosure of some of the polymers set out in claims 6 and 15, non-acrylic polymers are clearly suggested by the patent for use in providing similar coatings, and for the same art recognized purpose of modifying the release rate of the drug to be delivered. Further, while Ethicon Inc does not set out glass transition temperatures or the

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percentage of water for each polymer, these are measurements for which the ordinary practitioner can either access through reference texts such as the Merk Index, or value which would be expected to overlap given that the same broad classes of polymers are disclosed by the reference. As such, those of ordinary skill would have expected similar therapeutic results from the instantly claimed coating given the disclosure by Ethicon Inc. The instantly claimed coating would have been obvious to one of ordinary skill in the art at the time of invention given the disclosure of Ethicon Inc.

### ***Response to Arguments***

Applicant's arguments filed 03/19/2007 have been fully considered but they are not persuasive.

Applicant argues that there is no teaching in Ethicon for one of ordinary skill in the art to select a polymer with a particular glass transition temperature as define in claim1. In particular, applicant argues that there is not suggestion in Ethicon to select a polymer with less than 1 mass % of water controlling the rate of drug release. Further, applicant argues that there is no motivation for selection of polymers of certain glass transition temperatures.

However, as stated in the prior action, applicant is claiming properties which depend upon the particular polymer selected. Again, these values may be referenced in various art recognized chemical manuals. While applicant points to various factors upon

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which glass transition temperature may depend, nothing in the claims points to any specific factor or property beyond the generic description of the polymers. Even when classes of polymers are selected in claim 4, there is nothing in the claim particularly pointing out the molecular weight range or distribution, or ratio of monomers Applicant is therefore arguing limitations not found in the claims.

As such, the reference uses the same polymer classes to overcoat a bioactive containing layer. Applicant's broad claim of acrylic and no-acrylic polymers falls within the scope of the reference, and those of ordinary skill would expect similar rate limiting properties from the coatings instantly claimed. Barring a showing of unexpected results, the instant claims would have been obvious to one of ordinary skill in the art at the time of invention given the teachings of Ethicon.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Election/Restrictions***

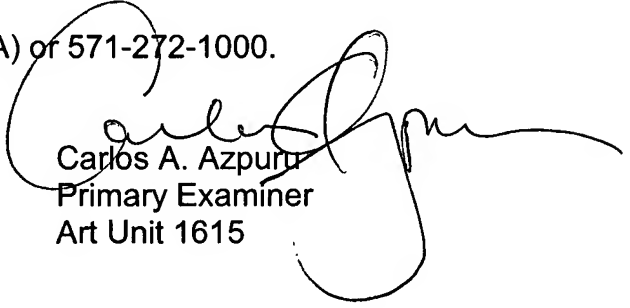
This application contains claims 5, 7, 13, 14 and 17-24 drawn to an invention nonelected with traverse in Paper No. 09202006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Carlos A. Azpur  
Primary Examiner  
Art Unit 1615

ca